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TITLE: Randomized, Controlled Trial of CBT Training for PTSD Providers

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14. ABSTRACT

The purpose of this 4 year, randomized trial and comparative effectiveness study is to design, implement and evaluate a cost effective, web based self-paced training program to provide skills-oriented continuing education for mental health professionals. The objective is to learn whether novel, internet-based training methods, with or without web-centered supervision, may provide an effective means to train increasing numbers of mental health providers in relevant, evidence-based clinical skills. The study will launch during the first quarter of the second year grant cycle. There are no research findings to date.

15. SUBJECT TERMS

There are no risks associated with participation.

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INTRODUCTION

Psychologically-based treatments and cognitive behavioral therapy (CBT) interventions have been shown to be effective in alleviating symptoms of Post-Traumatic Stress Disorder (PTSD) and related psychological health difficulties in Veterans and military personnel who suffer from these problems. To meet the increased service needs of Veterans with PTSD, new training methods need to be developed which are: 1) evidence-based, and 2) effective in modifying and sustaining changes in provider behavior. Methods of training/implementation must also be scalable, and feasible for delivery to large numbers of providers in cost-effective ways. Internet-based training is a promising new approach for meeting this need, but has received little systematic evaluation to date. Noting the urgency and high priority of this issue, Fairburn and Cooper (2011) have advocated strongly for the development of novel, internet-based training methods and innovative research designs to test the effectiveness of these new training methods. Our current program of research is aimed to address these needs.

The broad objective of our research is to design, implement and evaluate scalable and cost-effective new methods for training of mental health clinicians providing treatment services to veterans with PTSD. The randomized controlled trial (RCT) design is briefly as follows: eligible clinicians in the community and VHA will be randomly assigned in equal numbers to three parallel intervention condition: a) Web-based training plus web-centered supervision; b) Web-based training alone; and c) Training-as-usual control group. An equal number of clinician trainees from VHA (N=219) and the community (N=219) will be recruited and enrolled in the study over an 18-month period according to a randomized, stratified 24-week design.

Comprehensive assessments will be performed at baseline (T0), completion of training (T1), and at 3 month follow-up (T2). Participants randomized to the consultation condition will be exposed to a newly developed web-centered form of learning consultation. Measures of compliance and completion will assess adherence to protocol. Training effectiveness will be evaluated by means of a combination of objective (SPE) and self-report measures. The primary and secondary aims of the study are as follows:

Primary Aim: To compare an enhanced, internet-based training intervention combined with novel web-centered supervision, internet-based training intervention without web-centered supervision and a wait-list control with regard to improvements in two CBT-based skill areas (behavioral task assignment and chain analysis). We hypothesize that enhanced, internet-based training in conjunction with web-centered supervision will result in superior skills acquisition compared to internet training alone and that internet training alone will result in superior CBT skills than wait-list control.

Secondary Aim #1: To compare improvements in knowledge and attitudes following internet-based training with or without web-centered supervision and the control. We hypothesize that web-centered supervision will lead to greater improvements in CBT knowledge and perceived self-efficacy compared to internet-based training without supervision or a written training-only condition. We hypothesize similarly that internet-based training will be associated with improved outcomes in CBT knowledge and attitudes compared to a written training-only condition.

Secondary Aim #2: To compare improvements in skills acquisition in knowledge and attitudes following training in clinicians recruited from VHA mental health treatment settings compared to those providing services in civilian community-based clinics. We hypothesize that comparable

improvements will be achieved in the trainees from civilian community-based clinics compared to clinicians recruited from VHA centers.

Secondary Aim #3: To assess the relative efficiency of training, as measured by total time required for training in each condition, in addition to self-reported level of burden for clinicians. We hypothesize that internet-based training with or without web-centered supervision will be associated with increased time investment and burden relative to training-as-usual, but that absolute levels of burden will be low in the web training conditions.

This study will be the first of its kind to systematically compare web-based training interventions across treatment settings and provider groups (VHA vs Non-VHA). The study will also be unique in: 1) developing and testing of new web-enhanced training modules and a novel web-centered supervision model recently proposed by Fairburn & Cooper (2011); 2) development and implementation of a new patient-reported measure of clinician skill and competency; and 3) assessment of post-training maintenance of skills beyond the training period. Our focus on broad-based, generic CBT skills rather than more narrowly focused protocol-based skills is another innovative aspect of our proposed study. Finally, the use of standardized patient methodology for assessing outcomes of training, and planned comparisons with self-report and knowledge-based assessment, is another novel feature of our proposed study.

If successful, the study will promote a better standard of care for psychological health of Veterans and their families by evaluating technical feasibility of two training models in evidence-based skills for PTSD treatment providers and measuring their outcomes and effectiveness. If successful, the study will provide experimental support for broad implementation of these enhanced new training methods across a variety of treatment settings.

KEYWORDS

Behavioral Task Assignment (BTA)
Chain Analysis (CA)
Cognitive behavioral therapy (CBT)
Post-Traumatic Stress Disorder (PTSD)
Randomized controlled trial (RCT)
Standardized Patient (SP)

ACCOMPLISHMENTS

This section of the report will describe the research accomplishments associated with each task outlined in the approved Statement of Work (SOW).

Year 1:

- 1. Develop Web-based Training Materials
 - a. Develop and pre-test CBT instructional modules and materials
 - During the first year, the content development modules were desgined, developed and completed. Module content for the video clip development was finalized, including filming and final cut review.
 - b. Develop case material and demonstrations
 - i. During the first year of this project, the team developed multiple case portrayals for use in the video simulation interviews.
 - c. Prepare web-based supervision manual and materials

- i. During the first year of this project, the team created and finalized a manual and materials for the web-based supervision.
- d. Training content complete, reviewed by CBT expert consultants
 - i. A team of carefully selected expert content consultants, including Christopher Fairburn, MD, Amy Naugle, Ph.D., Gareth Holmen, Ph.D., and Brett T. Litz, Ph.D, were invited to serve as special consultants to the project based upon their extensive experience and knowledge in these content areas.
- e. Pilot test all study procedures and materials (prior to programming)
 - i. Pilot testing of the knowledge items was initiated with > 50 completed surveys collected and both qualitative and quantitative data collected. A combination of blueprinting and concept mapping approaches were used to identify key concepts and to generate specific knowledge assessment items. The assessment items were being pre-tested according to our study protocol and final items were later available at randomization.
- 2. Develop and Finalize Study Protocol and Measures
 - a. Eligibility criteria, exclusion criteria, screening protocol
 - i. During the first year of this project, the team finalized the eligibility criteria, exclusion criteria and screening protocol.
 - b. Sample frame, web contact methods, email lists identified
 - During the first year of the project, the team identified potential participants as well as identified existing email lists of participants through collaboration with community based groups.
 - 1. Email lists included: VHA mental health clinicians that have participated in the "clinical training program" at the National Center for PTSD in the past, VHA mental health clinicians who have not participated in the "clinical training program" at the NCPTSD, team leaders at the Vet Centers in the United States, and a registry of community practitioners who have agreed to volunteering pro bono to serve the needs of veterans (Give an Hour). A large number (6800) of community clinicians participate in this registry and our study has arranged access to this recruitment pool.
 - ii. Postcards were created to be disseminated at conferences and other mental health events to enhance recruitment activities in addition to the pre-defined email lists.
 - c. Standardized Patient Interviews scripted and pre-tested
 - A standardized patient interview script was created for assessing clinical skills prior to and following the training. It was pre-tested during year 1.
 Actors and interviewers were identified for the study.
 - d. Research measures and instruments developed and pre-tested
 - i. Knowledge and attitude questionnaires were developed for the study and were underwent pre-testing during year 1. Other measures were finalized based on findings from the first study (Ruzek et al., 2012).
 - e. Consent form drafted, human subjects protocol finalized
 - i. During the first year of this project, the web based consent form was created. The consent form and protocol were approved by both NERI and the Stanford IRBs. The terms of the study were clearly defined with an "accept" or "decline" participation button. All consent activities occurred through a secure web site.
 - f. NERI/VHA IRB approvals and USAMRMC HRPO human subject protocol approval

- i. The Protocol, Recruitment Materials, Informed Consent documents, applicable applications were approved by the New England Research Institutes, Inc (NERI) IRB on May 6, 2013. Revised Consent forms (version 4) were approved by the NERI IRB on June 20, 2013 to comply with the DoD requirements. The protocol was reviewed by the US Army Medical Research and Materiel Command (USAMRMC), Office of Research Protections (ORP), Human Research Protection Office (HRPO) and found to comply with applicable DOD, US Army, and USAMRMC human subjects protection requirements. This approval was dated July 2, 2013.
- 3. Develop, Pre-Test and Finalize Web Site and Instructional Program
 - a. VHA web host programmers provide specification and guidance to web programmers and database programmers
 - The team collaborated with the VHA NCPTSD to determine integration requirements for ultimately hosting the of the programmed in the construction of our web-based training program on an NCPTSD server. The site is fully tested and compliant with WCAG and 508 compliance requirements.
 - b. PTSD training material completed. All web training modules have been completed and were beta tested.
 - c. Web programming specifications completed
 - During the first year of this project, the web programming specifications were identified, content was finalized and web programming activities were initiated.

4. Develop Data Management System

- a. Flow chart all study steps, web data collection and database requirements
 - i. During the first year of this project, a design was created to show the steps in data collection to plan for programming of the DM system.
- b. Develop web-based data forms for all research measures
 - i. During the first year of this project, the team started the creation of webbased data forms.
- c. Program the database including project data entry forms
 - i. During this period, the team conducted initial programming activities of forms in preparation for the pilot.
- d. Program web usage statistics reports
 - i. An analysis plan was developed for selection and validation of knowledge items.
- e. Program automatic email reminders/interaction with web participants
 - i. During the first year of this project, the email reminder process had been reviewed and was an ongoing part of the data management activities.
- 5. Prepare Standardized Patient Rating Protocol
 - a. Develop and Pre-test Standardized Patient (SP) Rating Guide
 - i. Standardized patient case materials were developed and were in a pretesting phase during year 1.
 - ii. New rating scales had been developed and are were being pre-tested during year 1.
 - b. Training procedures were developed and pre-tested.

Year 2:

1. Develop and Finalize Study Protocol and Measures

- a. Web programming specifications were completed
- b. Web modules were programmed
- c. Beta testing of web program occurred

2. Develop Data Management System

- a. Programming of the database including project data entry forms was completed
- b. Programming of reports was completed
- c. Beta testing of all programmed pieces and interactivity was conducted
- d. Ongoing monitoring of study process
 - i. Recruitment started on 3/5/2014
 - ii. FPI was on 3/7/2014
 - iii. During the second year of this project, the team actively monitored data collection, data management, and the study process. We developed weekly reports for active tracking of recruitment and study processes, and met bi-weekly to discuss progress.

3. Prepare Standardized Patient Rating Protocol

- a. Develop and Pre Test Standardized Patient (SP) Rating Guide
 - i. During the second year of this project, the team developed the SP Rating Guide. Rating scales were developed, and underwent careful review for inter-rater reliability and finalization of all rating items, to assess adherence and competence for each training module.
- b. External Review of the SP Rating Guide and Methods
 - i. A metrics committee was formed, comprised of key study staff and external advisor Dr. Zafra Cooper (Oxford).
 - Our team developed the rating guide and methods were reviewed by the metrics committee, and Dr. Zafra Cooper (Oxford) assisted with final development and review.
- c. Training of Independent Study Raters to Concordance
 - i. The team hired and trained four study raters.

4. Develop Data Collection, Intervention and Standardized Patient Interviews

- a. Web screening of potential clinician applicants occurred.
- b. SP baseline interviews with eligible clinicians occurred.
- c. Automated random assignment of participants with Completed SP Interview by Web Program to Web-Course, Web-Course + Web- Based Supervision, or Control

5. Analysis and Evaluation

- a. Monitor Data Collection Rates and Data Quality
 - i. The team collaborated with the VHA NCPTSD to monitor the collection rates and data quality on a weekly basis.
- b. Create Interim and Final Analytical Data Sets
 - i. During the second year of this project, the initiation of the baseline data sets began.

Year 3:

- 1. Develop Data Management System
 - a. Ongoing monitoring of study process
 - i. Between years 2 and 3 of this project, the team actively monitored data collection, data management, and the study process. Bi-weekly reports

were developed for active tracking of recruitment and study processes, and met bi-weekly to discuss progress. Study enrollment was completed in April 2015 with a total of 420 participants (VA = 209, Community = 211), exceeding our targeted recruitment goal of 414 participants (207 per sector)

2. Prepare Standardized Patient Rating Protocol

- a. Develop and Pre Test Standardized Patient (SP) Rating Guide
 - i. The team developed the SP Rating Guide in year 2. During year 3, rating scales were developed and finalized.
- b. External review of SP rating guide and methods
 - During year 3, raters utilized the finalized rating forms to rate the SPs from BTA and CA. These ratings underwent continued analyses for interrater reliability.
- c. Training of Independent Study Raters to Concordance
 - i. The team hired and trained study raters for BTA and CA. Blinded independent ratings and reliability assessments began in Q2 of Year 2.

3. Data Collection, Intervention and Standardized Patient Interviews

- a. Schedule and Carry Out Post Training, Follow Up SP Interviews
 - i. This was an ongoing occurrence into year 3.

4. Analysis and Evaluation

- a. Monitor Data Collection Rates and Data Quality
 - i. The team collaborated with the VHA NCPTSD to monitor the collection rates and data quality on a weekly basis.
- b. Create Interim and Final Analytical Data Sets
 - i. During the second year of this project, the initiation of the data sets was scheduled to begin. This task continued into year 4. Final datasets will be completed in Year 5 (following approval of extension without funding).

Year 4:

- 1. Prepare Standardized Patient Rating Protocol
 - a. Training of Independent Study Raters to Concordance
 - i. All ratings were completed in year 4.
- 2. Data Collection, Intervention and Standardized Patient Interviews
 - a. Data collection was completed on January 7th, 2016.
 - b. A complete dataset was downloaded and saved to a secure server.
 - c. SP ratings rubric was finalized.
- 3. Analysis and Evaluation
 - a. Monitor Data Collection Rates and Data Quality
 - i. The team collaborated with the VHA NCPTSD to monitor the collection rates and data quality on a weekly basis.
 - ii. Data cleaning and recoding was performed.
 - b. Create Interim and Final Analytical Data Sets
 - During the second year of this project, the initiation of the data sets began. This task continued into year 4 and final datasets will be completed in year 5 (following approval of the extension without funding). A statistical analysis plan was developed.
 - c. Perform all analyses according to specification, share output and findings with all investigators

- i. Analysis/proposal plans for the baseline, main results, and web usage papers have been created and reviewed by the investigators.
- d. Author and co-author evaluation findings
 - i. All three papers are in the process of being written.
- e. Convene advisory meeting
 - i. All advisory personnel have been kept informed of study progress throughout the study duration.
 - ii. A final meeting will be held in year 5.

4. Other Items

- a. Conversion and long term hosting of the study website
 - i. NERI has completed conversion of the web-based training program from a Content Management System (CMS) to HTML, incorporating all training modules developed by NERI and the VA (Behavioral Task Assignment, Goal Setting, Motivational Interviewing, and supplemental videos for Chain Analysis), and removing the login required during the study period to allow for open access. NERI has provided final HTML files to the VA for long-term hosting. NERI remains available to discuss questions regarding hosting the HTML site on the VA/EES server.
 - ii. NERI will continue to host the study site until September, 2018, to allow the VA adequate time to identify a long-term hosting solution.
- b. CE/CME accreditation
 - i. All CE/CME certificates have been issued for completion of the training. Four types of accreditation were offered: Social Work, Nursing, CME, and Psychology. Participants received 5 credit hours for completion of this training. All participants who completed the follow-up assessment were eligible to receive certification. In order to receive a certificate, participants were required to complete a CE evaluation (administered at post-test, and re-sent to participants who did not complete it during the study), and pass the knowledge assessment (at either post-test or followup) with a score of 70% or higher in order to earn the certificate. If a participant did not pass the knowledge assessment during the study, they were sent a re-test of the knowledge questions following completion of their participation. Participants were allowed to take as many re-tests as necessary in order to pass the knowledge assessment. A number of participants opted out of receiving a CE certificate, or did not respond to our requests to complete a re-test. In total, 139 continuing education certificates were issued.
- c. Presentations of preliminary findings
 - Preliminary findings for baseline and main results data were presented at the Military Health System Research Symposium (MHSRS) in August 2016.
 - ii. Preliminary findings for web usage data were presented at the American Psychological Association (APA) 2016 Convention in August 2016.
 - iii. A Symposium will be presented at the International Society for Traumatic Stress Studies (ISTSS) 2016 Annual Meeting in November 2016, covering consultation, standardized patient methodology, and web usage results.

Final recruitment information is as follows (as of 1/7/2016):

Invitation Statistics

34,495 potential participants were invited to join the study

Registration Statistics

1609 registrant

Screener Statistics

Out of 1609 registrants...
998 participants have screened eligible
68 participants have screened ineligible
543 participants have not screened

Consent Statistics

Out of 998 participants screened eligible...
856 participants have consented
64 participants have not consented
78 participants have not completed the consent

Pre-test Statistics

Out of 856 participants consented...
613 participants have completed the pre-test

Standardized Patient 1 Statistics

Out of 613 participants who completed the pre-test... 420 participants have completed the SP1

Randomization Statistics

Out of 420 participants who completed the SP1...
420 participants have been randomized
66 participants have been randomized but have decided to not partake in the study (early termination)

Post-test/SP2 Statistics

Out of 420 participants who were randomized... 273 participants have completed the SP2 241 participants have completed the post-test

Follow-up Statistics

Out of the 420 participants who have been randomized ... 224 participants have completed the Follow-up

Standardized Patient 3 Statistics

Out of 420 participants who have been randomized... 244 participants have completed the SP3

KEY RESEARCH ACCOMPLISHMENTS

- Web-based and written training materials were finalized
- Video elements were implemented into the training website

- Training website was launched, to include Behavioral Task Assignment & Chain Analysis and Case Formulation
- CE accreditation was obtained for Psychology, Social Work, Nursing, and CME
- Standardized Patient Interview scripts were finalized, and actors were hired and trained
- Pre-test, post-test, and follow-up questionnaires were developed, finalized, and programmed
- All data collection forms were finalized, programmed, and tested in the data management system
- Reports to review ongoing statuses of all forms and subject progress were developed and finalized
- Subject recruitment methods were finalized and recruitment was started
- Subject management procedures for the entire study flow, including all email and phone communications were developed and executed
- IRB approval was sought and obtained for all necessary modifications, and continuing review approval was obtained.
- Recruitment goals were exceeded with a final randomization number of N = 420.
- All post-test and follow-up questionnaires were completed in October 2015.
- 139 continuing education certificates were issues.
- All data collection was completed on January 7th, 2016.
- Data cleaning, recording, and data set preparation has begun
- Statistical analysis plans were drafted for three manuscripts, and are in the process of finalization. Preliminary analyses have been completed.
- The development of three manuscripts (baseline, main results, web usage) are underway.

During the upcoming performance period, year 5, the team will focus on the following activities and milestones:

- Create final analytic data sets Data sets are being finalized. This task will continue into Year 5.
- 2. Perform all analyses according to specification During Year 5, the team will finalize SAPs for each proposal and perform statistical analyses to address study aims (above).
- Author and co-author evaluation findings During Year 5, findings will be analyzed and discussed in developed manuscripts. We anticipate submitted 3-4 papers prior to the termination of the grant.
- 4. Convene advisory meeting and project review During Year 5, the team will review study achievements and lessons learned.

To date there have been no risks associated with this project that have impeded its performance. With the complex nature of the data analysis, all data analysis and paper writing has not yet been completed. NERI has submitted a request for a first time Extension Without Funds to extend the performance period to September 29th, 2017 in order to complete all data analysis and manuscript writing.

Personnel receiving salary from this research effort are Raymond C. Rosen, Ph.D. (Partnering PI), Lisa Marceau, MPH (Co Investigator, Director), Ashley Wilkinson (Project Manager), Bernet Kato (Statistician), Brian Harty (Statistician), Julia Coleman (Media Manager), and Julia Dwyer (Senior Research Assistant).

REPORTABLE OUTCOMES

Dr. Rosen presented an update on the project to CDMRP leadership at the MOMRP meeting in Ft. Detrick in September 2016.

All presentations to date:

Title	Presenter	Conference Dates	
A Randomized Control Trial of Online Training for PTSD	Alie, G. & Graham, B.C.	April 2013	
Actor Fidelity and Training for Standardized Patient use in Clinical Research	Jordan, K.R. & Graham, B.C.	April 2014	
Web-centered Consultation for Online Training in PTSD Treatment: A Scalable Approach to Skill-building	Sardarian, S. & Graham, B.C.	April 2014	
Individual and Organizational Factors in Dissemination and Implementation of Skills following an Online Training for Clinicians Treating PTSD	Graham, B.C., Ruzek, J. & Lee, J. E.	May 1 – May 3, 2014	
Randomized, Controlled Trial of CBT Training for PTSD Providers: Project OUTFIT	Ruzek, J. & Rosen, R.	August 5 – August 6, 2014	
Project OUTFIT: Online User Training for Intervention in Trauma	Graham, B.C. & Ruzek, J.	April 28, 2015	
The Role of Organizational and Provider Factors in Community Interventions Across Diverse Systems.	Graham, B.C.	June 1, 2015	
Randomized, Controlled Trial of CBT Training for PTSD Providers: Project OUTFIT	R. Rosen	September 11, 2015	
Improving the Efficiency of Standardized Patient Assessment of Clinician Fidelity: A Comparison of Automated Actor-based and Manual Clinician-based Ratings	Graham, B.C.	September 25 – September 26, 2015	
Evaluating Clinicians' Use of a Web-based Training in Cognitive Behavioral Therapy for PTSD: Impact on Outcomes and Correlation with Self-Reported Use	Coleman, J.	August 6, 2016	
Assessment of Evidence-Based Training for Trauma Providers: Project OUTFIT Measures & Outcomes	Rosen, R.	August 15-18, 2016	
Evidence-Based Training of PTSD Providers: Results of a Randomized Controlled Trial of On-Line Training for VA and Community- based PTSD Providers	Rosen, R. & Wilkinson, A.	August 15-18, 2016	
ISTSS Symposium - Challenges in Development of Scalable, Effective Training for Mental Health Providers	R. Rosen, J. Ruzek, J. Coleman	November 11 th , 2016	

CONCLUSION

This training program focused on the development of evidence-based CBT skills to improve skills in providers treating Veterans and active duty military and to effectively engage patients in the treatment process. This innovative study will add new knowledge to our understanding of skills dissemination in PTSD provider care. We tested the hypotheses of the study in a rigorous, experimental design, and assessed outcomes of new web-based training modules and consultation methods. This study will provide data to assist researchers, military leaders, and treatment providers to better understand practical and theoretical implications for future training of mental health providers in the VHA and other health systems.

Data analysis, manuscript writing, and final advisory board meeting will occur over the next 12 months of grant activity (pending approval).

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- Fairburn, C. G., & Cooper, Z. (2011). Therapist competence, therapy quality, and therapist training. *Behaviour Research and Therapy, 49*, 373-378.
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Title: Randomized, Controlled Trial of CBT Training for PTSD Providers Proposal ID, Funding Source: W81XWH-12-1-0532



PI: Ray Rosen Org: New England Research Institutes, Inc.

Study/Product Aim(s)

The purpose of this study is to design, implement and evaluate a web based training program providing skills-oriented continuing education for mental health professionals.

- To compare improvements in knowledge and attitudes following internet-based training with or without web-centered supervision and the control.
- To compare improvements in skills acquisition in knowledge and attitudes following training in clinicians recruited from VHA mental health treatment settings compared to those providing services in civilian community-based clinics.
- To determine whether clinician implementation of skills assessed by means of a novel, patient-based measure of clinician skills implementation and effectiveness is predictive of changes in an objective (i.e., standardized patient) measure of skills
- To assess the relative efficiency of training, as measured by total time required for training in each condition, in addition to self-reported level of burden for clinicians.

Approach

The study will test a large-scale, Web-based method of training with 414 VA (n = 207) and community-based clinicians (n = 207). Subjects will be recruited to participate in the evidence-based skills training and will be randomly assigned to 1 of 3 groups: Interactive Web-based training only; interactive Web-based training plus post training Web-based consultation; or training as usual control. Effectiveness will be evaluated using an intent-to-train design. Post-training and 3-month follow up assessment will be conducted.

The objective is to learn whether novel, internetbased training methods, with or without webcentered supervision, may provide an effective means to train increasing numbers of mental health providers in relevant, evidence-based

clinical skills.

Award Amount: \$1,483,750.00

Accomplishments: Analysis of data for presentation and manuscript development is underway.

Timeline and Cost

Activities	CY12/CY13	CY13/CY14	CY14/CY15	CY15/CY16
Develop Web-based Training Materials				
Develop, Pre-Test and Finalize Web Site including Audio and video				
Develop / Finalize Study Protocol Measures				
Develop Data Management System				
Prepare SP Rating Protocol				
Data collect, Intervention, SP Interviews				
Analyses and manuscripts				
Estimated Budget	484,649	301,479	271,330	426,292

Updated: (210ct2016)

Goals/Milestones

CY12 Goal – Develop SP and Consultation protocols, design web program, develop DM System

- ✓ Content completed
- ✓ Video/audio created
- ✓ SP scripts developed
- ✓ Site programmed and tested
- ✓ DM system developed

CY13 Goals - Data collection

✓ Track metrics for subject recruitment and completion goals

CY14 Goals - Data collection

✓ Track metrics for subject recruitment and completion goals

CY15 Goals/CY16 Goals - Analyses and manuscripts

☐ Complete main results analyses and MS based on findings

Comments/Challenges/Issues/Concerns

We have recently submitted an Extension without funds to extend our end date to 29Sep2017.

Projected expenditure - 1,483,750

Actual Expenditure: \$1,377,288